UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,425	02/12/2004	Paul R. Sanberg	1372.129.PRC	4329

21901 7590 11/26/2008

SMITH HOPEN, PA
180 PINE AVENUE NORTH
OLDSMAR, FL 34677

EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
11/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,425	SANBERG ET AL.	
	Examiner	Art Unit	
	TAEYOON KIM	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-12 and 14-26* is/are pending in the application.

4a) Of the above claim(s) *19-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-12 and 14-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 5-12 and 14-26 are pending.

Response to Amendment/Arguments

Applicant's amendment and response filed on Apr. 16, 2007 has been received and entered into the case.

Claims 2-4 and 13 are canceled, claims 19-26 have been withdrawn from consideration as being drawn to non-elected subject matter, and claims 1, 5-12 and 14-18 have been considered on the merits. All arguments have been fully considered.

In the response to the claim rejection under 35 U.S.C.§103 based on Pittinger et al. in view of Erices et al., Edelberg et al., and Lim et al., applicant argued that although Erices teaches that umbilical cord blood (UCB) possesses mesenchymal progenitor cells, and that MPCs are precursors for bone marrow stromal cells, bone cartilage, muscle and connective tissue, Erices et al. fail to teach that mesenchymal cells may differentiate into cardiac muscle. It is acknowledged that Erices et al. do not particularly teach that the mesenchymal cells differentiate into cardiac muscle. Instead, Erices et al. generically teach that mesenchymal stem/progenitor cells can differentiate into muscle.

Applicant argued as if the claim rejection in the previous office action was solely based on the use of MPCs of Erices et al. in the place of MPCs of Pittinger et al. This is not the case. The rejection was based on the use of UCB of Erices et al. replacing the MPCs of Pittinger et al. (see p.3 of the previous office action). The rationale of such substitution is based on Erices et al. teaching MPCs present in the UCB, and Edelberg et al. teaching endothelial progenitor cells present in the UCB.

Since Pittinger et al. teach MPCs are precursors for cardiac myocytes, it is the examiner's position that the MPCs of Erices et al. from UCB would have the same property as the MPCs of Pittinger et al.

Furthermore, Edelberg et al. teach that cardiac myocytes are derived from endothelial progenitor cells from UCB (para. 18).

Therefore, it would have been obvious to a person of ordinary skill in the art to replace the MPCs of Pittinger et al. can be replaced with UCB cells of Erices et al. and Edelberg et al., which comprise both endothelial progenitor cells as well as MPCs capable of differentiating into cardiac myocytes, for the intended purpose of the method of Pittenger et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-12 and 14-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pittenger et al. in view of Erices et al. and Edelberg et al. in further view of Lim et al.

Pittenger et al. teach a method of regenerating cardiac muscle using mesenchymal stem cells (see abstract). Pittenger et al. teach human MSCs being introduced to the infarct zone (myocardial infarction; cardiac injury) to reduce the degree of scar formation and to augment ventricular function (treating a circulatory disorder; col.

4, lines 7-19). Pittenger et al. also teach direct or systemic administration (col. 2, lines 25-30) and an amount of cells for administration being 10-40x10^6 MSCs/ml (col. 4, lines 65-67).

Pittenger et al. do not teach MSCs being umbilical cord blood cells.

Erices et al. teach that umbilical cord blood (UCB) is a source for multipotent mesenchymal progenitor cells which differentiate into muscle (see entire document; esp. p.235, left col.).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to substitute MSCs of Pittenger et al. with UCB of Erices et al., which comprises mesenchymal progenitor cells, in the method of Pittenger et al.

The skilled artisan would have been motivated to make such a modification because Erices et al. teach that mesenchymal progenitor cells present in UCB is capable to differentiate into muscle, and Edelberg et al. teach that cardiac myocytes differentiated from endothelial precursor cells, which can be derived from umbilical cord blood (para. 18 and 24). Thus, a person of ordinary skill in the art would recognize UCB of Erices et al. as a suitable alternative to MSCs of Pittenger et al. for the same purpose of regenerating cardiac muscle cells in damaged heart.

Although Pittenger et al. in view of Erices et al. and Edelberg et al. do not teach the limitation of administering the UCB cell within approximately 48 hours after the onset of myocardial infarction, a person of ordinary skill in the art would recognize that the range of hours for administration of UCB cell is a result-effective variable. As such, the

variables would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by those references. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); >see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); ** In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Accordingly, the claimed invention was prima facie obvious to one of

ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

With regard to the limitation of the umbilical cord blood composition comprising at least 6 million white blood cells per milliliter, the use of UCB in a method of treating myocardial infarction as taught by Pittenger et al. in view of Erices et al. and Edelberg et al. inherently meets the limitation of the white blood cell contents, since Lim et al. teach that UCS contains about 11 million white blood cells per ml (see Table 1).

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Taeyoon Kim
AU-1651